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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-23

January 16, 2002

David P. Robinson, President
South East Instruments Corp.
3706 N.W. 97 Blvd.
Gainesville, Florida 32606

Dear Mr. Robinson:

During an inspection of your establishment located in Gainesville, Florida on December 3-4, 2001, FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer and distributor of ultrasonic scalers. Under section 201(h) the Federal Food, Drug, and Cosmetic Act (the Act), the ultrasonic scalers are medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. During the inspection the investigator documented violations of the Act resulting in the device being adulterated within the meaning of section 501(h) of the Act. The Act requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the device is adulterated in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation as follows:

1. Your firm failed to document action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems as required by 21 CFR 820.100(b). For example, your firm failed to document actions taken to correct and prevent burns to a patient's mouth as referenced in a complaint dated June 7, 2000; and to verify actions taken by the footswitch supplier to correct and prevent reported electrical shocks received by a customer (FDA 483, Observation #1).

2. Your firm failed to establish and implement adequate complaint procedures to ensure that all complaints are evaluated to determine reportability under the Medical Device Report (MDR) regulation as required by 21 CFR 820.198(a)(3). Your firm fails to obtain adequate information of complaints in order to determine reports required to be made under MDR, such as a

complaint in 1997 referencing burns to a patient's mouth and a customer receiving a shock from a footswitch in 1998 (FDA 483, Observation #2).

3. Your firm failed to establish and document procedures necessary to control environmental conditions as required by 21 CFR 820.70(c). For example, there are no written procedures addressing electrostatic discharge (ESD) (FDA 483, Observation #3).

4. Your firm failed to establish and implement adequate design control procedures as required by 21 CFR 820.30(a). For example, device labeling and packaging are not addressed in your design control procedures (FDA 483, Observation #4).

5. Your firm failed to identify, analyze, and document existing and potential causes of non-conforming product and other quality problems as required by 21 CFR 820.100(a)(1). For example, you do not analyze complaints received concerning devices one year or older and there is no documentation covering in-process rejects (FDA 483, Observation #5).

6. Your firm failed to establish and implement documentation of corrective and preventive actions as required by 21 CFR 820.100(b). For example, you don't have a written Corrective and Preventive Action SOP (FDA 483, Observation #6).

7. Your firm failed to establish and implement procedures for conducting quality audits as required by 21 CFR 820.22. For example, your quality audit procedure fails to address Corrective and Preventive Actions (CAPA) and Design Controls (FDA 483, Observation #7).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District